

WHAT IS CLAIMED IS:

Sub
A1

1. A sterilization system for a medical product, comprising:
 - a) a radiation source which is configured to emit a radiation dose sufficient to sterilize a medical product;
 - b) a calorimeter which is configured to be irradiated by said source with a dose of radiation equivalent to a sterilizing radiation dose for the medical product; and
 - c) a calorimeter controller for determining the radiation dosage given to the calorimeter from the difference between the temperature of the calorimeter before and after the irradiation of the calorimeter, the temperature difference being a function of the radiation dose received from the radiation source.
2. The sterilization system for a medical product of claim 1, further comprising a conveyor system which is configured to receive the medical product and the calorimeter and to convey the medical product and the calorimeter to the radiation source.
3. The sterilization system for a medical product of claim 1, wherein said controller comprises an automatic controller.
4. The sterilization system for a medical product of claim 3, wherein said automatic controller comprises a computer-controlled automatic controller.

Sub
A.1
cont

5 A method for sterilizing a medical product, comprising:

- providing a calorimeter control system and a validated thermistor calorimeter having a validated resistance-temperature calibration relationship and a validated temperature-dosage calibration relationship;
- measuring an initial calorimeter temperature;
- irradiating the calorimeter with a dose of radiation from a radiation source;
- measuring a subsequent calorimeter temperature before significant heat loss has occurred;
- determining the radiation dose using a calculated temperature difference between said initial temperature and subsequent temperature measurements, and using said resistance-temperature and said temperature-dosage calibration relationships;
- repeating the preceding steps at an interval determined by said calorimeter controller;
- irradiating said medical product with a dose of radiation from the radiation source; and
- reporting said determined radiation dose.

6. A sterilization system for a medical product, comprising a controlled radiation source effective to provide a dose of radiation along a radiation path, a calorimetry controller configured to perform the steps of a radiation dosimetry

Sub
A:
Cont

control method, and a calorimeter.

7. The sterilization system for a medical product of claim 6, further comprising a conveyor effective to convey said thermistor calorimeter through said radiation path within a short time.

8. The sterilization system for a medical product of claim 7, wherein said conveyor is effective to convey the thermistor calorimeter along a short, closed-loop route at a rate effective to convey the thermistor calorimeter from a starting position to an ending position within a short time.

9. The sterilization system for a medical product of claim 8, wherein said controlled radiation source comprises a high dose-rate radiation source.

10. The sterilization system for a medical product of claim 9, wherein said high dose-rate radiation source is an electron radiation source effective to provide a dose of electron beam radiation.

11. A routine dosimetry method for determining and reporting a radiation dose for quality control of a radiation process, comprising:

providing a calorimeter control system and a validated thermistor calorimeter having a validated resistance-temperature calibration relationship

Sub
A-
cont

and a validated temperature-dosage calibration relationship;

measuring an initial calorimeter temperature;

irradiating the calorimeter with a dose of radiation from a radiation source;

measuring a subsequent calorimeter temperature before significant heat loss has occurred;

determining the radiation dose using a calculated temperature difference between said initial temperature and subsequent temperature measurements, and using said resistance-temperature and said temperature-dosage calibration relationships;

repeating the preceding steps at an interval determined by said calorimeter controller; and

reporting said radiation dose.

12. The method of claim 11, wherein the step of measuring a subsequent calorimeter temperature occurs within about 30 minutes after irradiating the calorimeter.

13. The method of claim 11, wherein the step of measuring a subsequent calorimeter temperature occurs within about 15 minutes after irradiating the calorimeter.

14. The method of claim 11, wherein the irradiating step comprises movement

Sub
A,
Cont.

of the validated thermistor calorimeter from a starting position to an ending position by a conveyor along a route.

15. The method of claim 14, wherein said route is a short, closed-loop route and the thermistor calorimeter is conveyed along the route at a rate effective to convey the thermistor calorimeter from its starting position to its ending position within a short time.

16. The method of claim 15 wherein said short time comprises a time of less than about 30 minutes.

17. The method of claim 15 wherein said short time comprises a time of less than about 15 minutes.

18. The method of claim 11 wherein the radiation source comprises a high dose-rate radiation source.

19. The method of claim 11, where the radiation dose is between about 0.1 kGy to about 100 kGy.

20. The method of claim 11, where the radiation dose is between about 2 kGy to about 70 kGy.

Sub
A17
Conf

21. The method of claim 11, where the radiation dose is between about 3 kGy to about 40 kGy.

22. A routine dosimetry control method for determining at intervals and reporting an acceptable radiation dose in a radiation process, said routine dosimetry method comprising routine measurements with a thermistor calorimeter having a resistance-temperature calibration relationship, a temperature-dosage calibration relationship and a maximum lifetime dose, the method comprising:

determining whether a calorimeter has a valid resistance-temperature relationship and a valid temperature-dose relationship, where a valid resistance-temperature relationship and a valid temperature-dose relationship comprise relationships in which a dose determined using the resistance-temperature and temperature-dose relationships and a dose traceable to a dose determined by a national calibration laboratory dose measurement match to within a specified degree;

determining whether a calorimeter has received less than a maximum lifetime radiation dose;

determining that a calorimeter is a validated calorimeter if it has a valid resistance-temperature relationship and a valid temperature-dose relationship and has received less than a maximum lifetime radiation dose;

measuring an initial calorimeter temperature of a validated calorimeter;

irradiating said validated calorimeter with a dose of radiation from a radiation source;

measuring a subsequent calorimeter temperature of said validated calorimeter before significant heat loss has occurred;

determining a radiation dose using a calculated temperature difference between said initial calorimeter temperature and said subsequent calorimeter temperature measurements, and using said resistance-temperature and said temperature-dosage relationships;

determining whether said radiation dose is an acceptable radiation dose;

determining an interval;

repeating the preceding steps after said interval; and

reporting said radiation dose.

23. The method of claim 22, wherein the step of measuring a subsequent calorimeter temperature occurs within about 30 minutes after irradiating a validated calorimeter.

24. The method of claim 22, wherein the step of measuring a subsequent calorimeter temperature occurs within about 15 minutes after irradiating a validated calorimeter.

25. The routine dosimetry control method of claim 22 wherein the radiation

source is a high dose-rate radiation source.

26. The routine dosimetry control method of claim 22, where the acceptable radiation dose is a radiation dose between about 0.1 kGy to about 100 kGy.

27. The routine dosimetry control method of claim 22, where the acceptable radiation dose is a radiation dose between about 2 kGy to about 70 kGy.

28. The routine dosimetry control method of claim 22, where the acceptable radiation dose is a radiation dose between about 3 kGy to about 40 kGy.

29. The routine dosimetry control method of claim 22, wherein the specified degree of match between a dose traceable to a dose determined by a national calibration laboratory dose measurement and the dose determined using the resistance-temperature and temperature-dose relationships is less than about 15 %.

30. The routine dosimetry control method of claim 22, wherein the specified degree of match between a dose traceable to a dose determined by a national calibration laboratory dose measurement and the dose determined using the resistance-temperature and temperature-dose relationships is less than about 5 %.

Sub
A:
copy

31. A system for routine dosimetry for quality control of a radiation process, comprising a controlled radiation source effective to provide a dose of radiation along a radiation path, a calorimetry controller configured to perform the steps of a radiation dosimetry control method, and a calorimeter.

32. The system of claim 31, further comprising a conveyor effective to convey said thermistor calorimeter through said radiation path within a short time.

33. The system of claim 32, wherein said conveyor is effective to convey the thermistor calorimeter along a short, closed-loop route at a rate effective to convey the thermistor calorimeter from a starting position to an ending position within a short time.

34. The system of claim 31, wherein said controlled radiation source comprises a high dose-rate radiation source.

35. The system of claim 34, wherein said high dose-rate radiation source is an electron radiation source effective to provide a dose of electron beam radiation.

36. The system of claim 35, wherein the dose of electron beam radiation is between about 0.1 kGy to about 100 kGy.

Sup
A
CMT

37. The system of claim 35, wherein the dose of electron beam radiation is between about 2 kGy to about 70 kGy.

38. The system of claim 35, wherein the dose of electron beam radiation is between about 3 kGy to about 40 kGy.

39. The method of claim 11, wherein said calorimeter is a thermistor calorimeter and said measuring steps comprise a step of contacting said thermistor calorimeter with a resistance measuring device.

40. The system of claim 31, wherein said calorimeter is a thermistor calorimeter, and further comprising a movable robotic arm having a resistance measuring device effective to contact the thermistor calorimeter and to obtain a resistance measurement therefrom.

41. The system of claim 31, wherein the steps that said calorimeter controller is configured to perform comprise the steps of accepting for use only validated calorimeters, determining whether the target radiation dose from said controlled radiation source has been changed, maintaining said interval constant if said target radiation dose has not been changed, prompting a routine calorimeter dosimetry if said target radiation dose has been changed, and managing the printing of a process report.

Sub
A-1
C10X

42. A method for radiation processing of an item, comprising:

- providing a calorimeter control system and a validated thermistor calorimeter having a validated resistance-temperature calibration relationship and a validated temperature-dosage calibration relationship;
- measuring an initial calorimeter temperature;
- irradiating the calorimeter with a dose of radiation from a radiation source;
- measuring a subsequent calorimeter temperature before significant heat loss has occurred;
- determining the radiation dose using a calculated temperature difference between said initial temperature and subsequent temperature measurements, and using said resistance-temperature and said temperature-dosage calibration relationships;
- repeating the preceding steps at an interval determined by said calorimeter controller;
- irradiating said item with a dose of radiation from the radiation source; and
- reporting said determined radiation dose.

43. The system for routine dosimetry of claim 31, wherein said controller comprises an automatic controller.

44. The system of routine dosimetry of claim 43, wherein said automatic controller comprises a computer-controlled automatic controller.